Health Care Financing Administration Rulings

On Medicare, Medicaid, Professional Standards Review and Related Matters

U.S. Department of Health and Human Services
Health Care Financing Administration Rulings

HCFA 10009

HCFA Rulings

Department of Health and Human Services

Health Care Financing Administration

Ruling No. **HCFAR-82-1 Through 86-1**

Date **July 1986**

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization, and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

The forward to the attached **Rulings** indicates that they have been previously issued and are being compiled in this format for the first time. We are reissuing them in a looseleaf form so that future **Rulings** may be easily interfiled and obsolete **Rulings** deleted.

FOREWARD

Programs of the Health Care Financing Administration - including Medicare, Medicaid, and Utilization and Quality Control Peer Review Organizations - affect millions of people throughout the United States. To understand these programs fully, the administrative instructions and manuals that guide staffs of Federal and State agencies and HCFA contractors in implementing the programs are accessible to the public. In addition, selected decisions (HCFA Rulings) of the agency are published under the Administrator's authority to show how particular provisions of the statute and regulations are interpreted and applied.

Thus, in publishing HCFA Rulings, HCFA's intent is to observe the spirit of the Freedom of Information Act: to keep the public informed about the agency's handling of the public's business. This particular set of HCFA Rulings contains Rulings, including an illustrative case decision, that serve as binding precedents upon those who administer the HCFA programs and upon those who serve as hearing officials in various program appeals. These Rulings are compiled in order to promote consistency in interpretation of policy and in adjudication of disputes.

This HCFA Rulings should be of use to Medicare beneficiaries, Federal and State employees who administer the programs, intermediaries, carriers, other HCFA contractors, providers and suppliers of services under the programs, attorneys, court and hearing personnel, and interested members of the public.

The Rulings published here, except for HCFAR 82-2c and HCFAR 86-1, are reprinted substantially as they appeared in the Federal Register. Where necessary we have updated citations and corrected typographical errors.

Additional or explanatory material is indicated by footnotes. HCFAR 82-2c is a court case, as identified by the suffix c following the Ruling (i.e., HCFAR 82-2c), and is reprinted substantially as it appeared in the Federal Digest. HCFAR 86-1 was distributed by HCFA directly to Federal and State employees who administer or are involved in appeals under Medicare or Medicaid, and to the contractors who implement the programs.

William L. Roper, M.D.
Administrator
Health Care Financing
Administration

HCFAR 82-1 HCFAR 86-1
Publication No. HCFA 10009

Contents

The HCFA Rulings in this publication are arranged chronologically according to their issuance number (e.g., HCFAR 82-1, HCFAR 82-2). As a reader aid, we list the Rulings below by subject matter, and chronologically within each grouping.

MEDICARE PROGRAM

Hospital and Supplementary Medical Insurance Benefits (Parts A and B)

Exclusion from Medicare Coverage of DMSO[1] for Conditions Other Than Interstitial Cystitis

HCFAR 82-1

Purpose: This Ruling restates HCFA policy regarding Medicare coverage of DMSO.

Citations: Section 1862(a)(1) of the Social Security Act; 42 U.S.C. 1395y(a)(1); 42 CFR 405.310(k); 20 CFR 422.40; 47 FR 41867, September 22, 1982.

Pertinent History: The Medicare statute prohibits payment for any expenses incurred for items or services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (section 1862(a)(1) of the Act). HCFA has interpreted this statutory provision to exclude from Medicare coverage medical and health care services and items that are not demonstrated to be safe and effective by acceptable clinical evidence. HCFA's source of medical advice on issues of medical safety and efficacy of services and items is the Public Health Service (PHS).

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[1] "DMSO" stands for dimethyl sulfoxide.

DMSO has been used as an industrial solvent since the 1940s. In 1959, it was found to be useful in protecting biological tissues from damage when they are preserved by freezing. In 1963, DMSO was reported to have medicinal properties and an investigational new drug application for the study of its use in humans was approved by the Food and Drug Administration (FDA). Testing was halted, however, in 1965 after experiments in animals indicated that DMSO had adverse effects on the eyes. Experiments were resumed the following year in light of the lack of evidence of eye damage in humans.

In 1972, the FDA asked the National Academy of Sciences—National Research Council to evaluate all the data available to the FDA on use of DMSO in humans. A committee appointed by the Academy concluded that only a very small number of scientific reports could be used as the basis for scientific conclusions on the toxicity and effectiveness of DMSO. Further, the committee made the following conclusions:

- The evidence on DMSO does not warrant the general approval of the drug. There is suggestive evidence that DMSO may be effective in the treatment of acute traumatic injury and nontraumatic painful shoulder and in relieving the pain of rheumatoid arthritis.

- DMSO produces side effects, particularly of the skin, in many persons. In rare cases, DSMO has been linked to discolored patches of skin in humans. Also, when tested in some species of laboratory animals, DMSO altered the lens of the eye.

- o DMSO should be restricted to investigational use until it can be clearly demonstrated that its therapeutic effects are sufficient to risk the side effects it may cause.
- o More reliable data are needed on the possible adverse effects and on the way DMSO works in the body.

The FDA approved DMSO for use in the symptomatic relief of chronic interstitial cystitis in 1978. HCFA consulted with PHS when preparing this ruling and again received advice that there is still insufficient evidence to establish that DMSO is safe and effective in conditions other than interstitial cystitis. The drug is currently being tested for other conditions.

Ruling: DMSO is not established to be safe and effective for any use other than interstitial cystitis; therefore, the use of DMSO for conditions other than interstitial cystitis is excluded from Medicare coverage under the authority of section 1862(a)(1) of the Act.

Effective Date: April 20, 1982

MEDICARE PROGRAM

Supplementary Medical Insurance Benefits (Part B)

Constitutionality of Part B Fair Hearing Procedures

42 CFR Part 405, Subpart H HCFAR 82-2c

Schweiker v. McClure, et al., U.S. Supreme Court, 456 U.S. 188 (1982).

Due process of law requires impartiality on the part of persons functioning in a quasi-judicial capacity, including appointed and employed carrier hearing officers who make final dispositions following a hearing of appealed Medicare Part B claims.

Held:

Part B hearing procedures do not violate due process requirements.

A presumption applies that carrier hearing officers are unbiased. This presumption may be rebutted by a showing of conflict of interest or other reason for disqualification. The factual findings in this case reveal no disqualifying interest. There is no basis in the record for concluding that the carriers themselves are biased, inasmuch as Part B claims are not paid from their own funds but rather from Federal funds, and the salaries of the hearing officers also are paid from Federal funds. Additionally, the Secretary has provided adequate instructions for carriers to follow to ensure that carrier-appointed hearing officers are qualified. It has not been shown that additional procedures, such as a further hearing conducted by a Government-employed Administrative Law Judge, would reduce the risk of erroneous deprivation of Part B benefits.[1]

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[1]This headnote was prepared by HCFA, not the Supreme Court.

456 U.S. 188, 72 L.Ed. 2d 1
Richard S. SCHWEIKER, Secretary of
Health and Human Services,
Appellant,
v.
William McClure et al.
No. 81-212.
Argued March 1, 1982.
Decided April 20, 1982.

Justice POWELL, delivered the opinion of the Court.

The question is whether Congress, consistently with the requirements of due process, may provide that hearings on disputed claims for certain Medicare payments be held by private insurance carriers, without a further right of appeal.

I

Title XVIII of the Social Security Act, 79 Stat. 291, as amended, 42 U.S.C. §1395 et seq. (1976 ed. and Supp. IV), commonly known as the Medicare program, is administered by the Secretary of Health and Human Services. It consists of two parts. Part A, which is not at issue in this case, provides insurance against the cost of institutional health services, such as hospital and nursing home fees. §§1395c-1395i-2 (1976 ed. and Supp. IV). Part B is entitled "Supplementary Medical Insurance Benefits for the Aged and Disabled." It covers a portion (typically 80%) of the cost of certain physician services, outpatient physical therapy, X-rays, laboratory tests, and other medical and health care. See §§1395k, 1395l, and 1395x(s) (1976 ed. and Supp. IV). Only persons 65 or older or disabled may enroll, and eligibility does not depend on financial need. Part B is financed by the Federal Supplementary Medical Insurance Trust Fund. See §1395t (1976 ed. and Supp. IV). This Trust Fund in turn is funded by

appropriations from the Treasury, together with monthly premiums paid by the individuals who choose voluntarily to enroll in the Part B program. See §§1395j, 1395r, and 1395w (1976 ed. and Supp. IV). Part B consequently resembles a private medical insurance program that is subsidized in major part by the Federal Government.

Part B is a social program of substantial dimensions. More than 27 million individuals presently participate, and the Secretary pays out more than $10 billion in benefits annually. Brief for Appellant 9. In 1980, 158 million Part B claims were processed. Ibid. In order to make the administration of this sweeping program more efficient, Congress authorized the Secretary to contract with private insurance carriers to administer on his behalf the payment of qualifying Part B claims. See 42 U.S.C. §1395u (1976 ed. and Supp. IV). (In this case, for instance, the private carriers that performed these tasks in California for the Secretary were Blue Shield of California and the Occidental Insurance Co.) The congressional design was to take advantage of such insurance carriers' "great experience in reimbursing physicians." H.R. Rep. No. 213, 89th Cong., 1st Sess., 46 (1965). See also 42 U.S.C. §1395u(a); S. Rep. No. 404, 89th Cong., 1st Sess., 53 (1965).

The Secretary pays the participating carriers' costs of claims administration. See 42 U.S.C. §1395u(c). In return, the carriers act as the Secretary's agents. See 42 CFR §421.5(b) (1980). They review and pay Part B claims for the Secretary according to a precisely specified process. See 42 CFR part 405, Subpart H (1980). Once the carrier has been billed for a particular service, it decides initially whether the services were medically necessary,

whether the charges are reasonable, and whether the claim is otherwise covered by Part B. See 42 U.S.C. §1395y(a) (1976 ed. and Supp. IV); 42 CFR §405.803(b)(1980). If it determines that the claim meets all these criteria, the carrier pays the claim out of the Government's Trust Fund—not out of its own pocket. See 42 U.S.C. §§1395u(a)(1), 1395u(b)(3), and 1395u(c) (1976 ed. and Supp. IV).

Should the carrier refuse on behalf of the Secretary to pay a portion of the claim, the claimant has one or more opportunities to appeal. First, all claimants are entitled to a "review determination," in which they may submit written evidence and arguments of fact and law. A carrier employee, other than the initial decision maker, will review the written record de novo and affirm or adjust the original determination. 42 CFR §§405.807-405.812 (1980); McClure v. Harris, 503 F. Supp. 409, 411 (ND Cal. 1980). If the amount in dispute is $100 or more, a still-dissatisfied claimant then has a right to an oral hearing. See 42 U.S.C. §1395u(b)(3)(C); 42 CFR §§405.820-405.860 (1980). An officer chosen by the carrier presides over this hearing. §405.823. The hearing officers "do not participate personally, prior to the hearing [stage], in any case [that] they adjudicate." 503 F. Supp., at 414. See 42 CFR §405.824 (1980).

Hearing officers receive evidence and hear arguments pertinent to the matters at issue. §405.830. As soon as practicable thereafter, they must render written decisions based on the record. §405.834. Neither the statute nor the regulations make provision for further review of the hearing officer's decision.[1] See United States v. Erika, Inc., 456 U.S. 201, 102 S. Ct. 1650, 72 L. Ed. 2d 12.

1. Hearing officers may decide to reopen proceedings under certain circumstances. See 42 CFR §§405.841-405.850 (1980).

II

This case arose as a result of decisions by hearing officers against three claimants.[2] The claimants, here appellees, sued to challenge the constitutional adequacy of the hearings afforded them. The District Court for the Northern District of California certified appellees as representatives of a nationwide class of individuals whose claims had been denied by carrier-appointed hearing officers. 503 F. Supp., at 412-414. On cross-motions for summary judgment, the court concluded that the Part B hearing procedures violated appellees' right to due process "insofar as the final, unappealable decision regarding claims disputes is made by carrier appointees . . . ." Id., at 418.

The court reached its conclusion of unconstitutionality by alternative lines of argument. The first rested upon the principle that tribunals must be impartial. The court thought that the impartiality of the carrier's hearing officers was compromised by their "prior involvement and pecuniary interest." Id., at 414. "Pecuniary interest" was shown, the District Court said, by the fact that "their incomes as hearing officers are entirely dependent upon the carrier's

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2. Appellee William McClure was denied partial reimbursement for the cost of an air ambulance to a specially equipped hospital. The hearing officer determined that the air ambulance was necessary, but that McClure could have been taken to a hospital closer to home. Appellee Charles Shields was allowed reimbursement for a cholecystectomy but was denied reimbursement for an accompanying appendectomy. The hearing officer reasoned that the appendectomy was merely incidental to the cholecystectomy. Appellee "Ann Doe" was denied reimbursement for the entire cost of a sex-change operation. The hearing officer ruled that the operation was not medically necessary.

decisions regarding whether, and how often, to call upon their services."[3] Id., at 415. Respecting "prior involvement," the court acknowledged that hearing officers personally had not been previously involved in the cases they decided. But it noted that hearing officers "are appointed by, and serve at the will of, the carrier [that] has not only participated in the prior stages of each case, but has twice denied the claims [that] are the subject of the hearing," and that five out of seven of Blue Shield's past and present hearing officers "are former or current Blue Shield employees."[4] Id., at 414. (Emphasis in original.) See also 42 CFR §405.824 (1980). The District Court thought these links between the carriers and their hearing officers sufficient to create a constitutionally intolerable risk of hearing officer bias against claimants.

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3. The District Court recognized that hearing officer salaries are paid from a federal fund and not the carrier's resources. McClure v. Harris, 503 F. Supp. 409, 415 (1980).

4. In this connection, the court referred to the judicial canon requiring a judge to disqualify himself from cases where a "'lawyer with whom he previously practiced law served during such association as a lawyer concerning the matter.'" 503 F. Supp., at 414-415, quoting Judicial Conference of the United States, Code of Judicial Conduct, Canon 3C(1)(b). The court found that application to hearing officers of standards more lax than those applicable to the judiciary posed "a constitutionally-unacceptable risk of decisions tainted by bias." 503 F. Supp., at 415.

Additionally, the court thought it significant that "no meaningful, specific selection criteria govern[ed] the appointment of hearing officers" and that hearing officers were trained largely by the carriers whose decisions they were called upon to review. Ibid.

The District Court's alternative reasoning assessed the costs and benefits of affording claimants a hearing before one of the Secretary's administrative law judges, "either subsequent to or substituting for the hearing conducted by a carrier appointee." 503 F. Supp., at 415. The court noted that Mathews v. Eldridge, 424 U.S. 319, 335, 96 S. Ct. 893, 903, 47 L. Ed. 2d 478 (1976), makes three factors relevant to such an inquiry:

> "First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail."

Considering the first Mathews factor, the court listed three considerations tending to show that the private interest at stake was not overwhelming.[5] The court then stated, however, that "it cannot be gainsaid" that denial of a Medicare beneficiary's claim to reimbursement may impose "considerable hardship." 503 F. Supp., at 416.

As to the second Mathews factor of risk of erroneous deprivation and the probable value of added process, the District Court found the record "inconclusive." 503 F. Supp., at 416. The court cited statistics showing that the

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5. "Eligibility for Part B Medicare benefits is not based on financial need. Part B covers supplementary rather than primary services. Denial of a particular claim in a particular case does not deprive the claimant of reimbursement for other, covered, medical expenses." Id., at 416.

two available Part B appeal procedures frequently result in reversal of the carriers' original disposition.[6] But it criticized these statistics for failing to distinguish between partial and total reversals. The court stated that hearing officers were required neither to receive training nor to satisfy "threshold criteria such as having a law degree." Ibid. On this basis it held that "it must be assumed that additional safeguards would reduce the risk of erroneous deprivation of Part B benefits." Ibid.

On the final Mathews factor involving the Government's interest, the District Court noted that carriers processed 124 million Part B claims in 1978. 503 F. Supp., at 416. The court stated that "[o]nly a fraction of those claimants pursue their currently-available appeal remedies," and that "there is no indication that anything but an even smaller group of claimants will actually pursue [an] additional remedy" of appeal to the Secretary. Ibid. Moreover, the court said, the Secretary already maintained an appeal procedure using administrative law judges for appeals by Part A claimants. Increasing the number of claimants who could use this Part A administrative appeal "would not be a cost-free change from the status quo, but neither should it be a costly one." Ibid.

Weighing the three Mathews factors, the court concluded that due process required additional procedural protection over that presently found in the Part B hearing procedure. The court ordered that the appellees were entitled to a

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6. "[Appellant] establish[es] that between 1975 and 1978, carriers wholly or partially reversed, upon 'review determination,' their initial determinations in 51-57 percent of the cases considered. Of the adverse determination decisions brought before hearing officers, 42-51 percent of the carriers' decisions were reversed in whole or in part." Ibid.

de novo hearing of record conducted by an administrative law judge of the Social Security Administration.[7] App. to Juris. Statement 36a. We noted probable jurisdiction, 454 U.S. 890, 102 S. Ct. 384, 70 L. Ed. 2d 204 (1981), and now reverse.

III

A

[1,2] The hearing officers involved in this case serve in a quasi-judicial capacity, similar in many respects to that of administrative law judges. As this Court repeatedly has recognized, due process demands impartiality on the part of those who function in judicial or quasi-judicial capacities. E.g., Marshall v. Jerrico, Inc., 446 U.S. 238, 242-243, and n. 2, 100 S. Ct. 1610, 1613, and n. 2, 64 L. Ed. 2d 182 (1980). We must start, however, from the presumption that the hearing officers who decide Part B claims are unbiased. See Withrow v. Larkin, 421 U.S. 35, 47, 95 S. Ct. 1456, 1464, 43 L. Ed. 2d 712 (1975); United States v. Morgan, 313 U.S. 409, 421, 61, S. Ct. 999, 1004, 85 L. Ed. 1429 (1941). This presumption can be rebutted by a showing of conflict of interest or some other

7. The court added that appellees "are not entitled to further appeal or review of the Administrative Law Judge's decision". App. to Juris. Statement 36a.

specific reason for disqualification.[8] See Gibson v. Berryhill, 411 U.S. 564, 578-579, 93 S. Ct. 1689, 1697-98, 36 L. Ed. 2d488 (1973); Ward v. Village of Monroeville, 409 U.S. 57, 60, 93 S. Ct. 80, 83, 34 L. Ed. 2d 267 (1972). See also In re Murchison, 349 U.S. 133, 136, 75 S. Ct. 623, 625, 99 L. Ed. 942 (1955) ("to perform its high function in the best way 'justice must satisfy the appearance of justice'") (quoting Offutt v. United States, 348 U.S. 11, 14, 75 S. Ct. 11, 13, 99 L. Ed. (1954)). But the burden of establishing a disqualifying interest rests on the party making the assertion.

[3] Fairly interpreted, the factual findings made in this case do not reveal any disqualifying interest under the standard of our cases. The District Court relied almost exclusively on generalized assumptions of possible interest, placing special weight on the various connections of the hearing officers with the private insurance carriers.[9] The difficulty with this reasoning is that these connections

8. The Secretary's regulations provide for the disqualification of hearing officers for prejudice and other reasons. See 42 CFR §405.824 (1980); App. 23-25. Appellees neither sought to disqualify their hearing officers nor presently make claims of actual bias. Tr. of Oral Arg. 34 (argument of counsel for appellees).

9. Before this Court, appellees urge that the Secretary himself is biased in favor of inadequate Part B awards. They attempt to document this assertion—not mentioned by the District Court—by relying on the fact that the Secretary both has helped carriers identify medical providers who allegedly bill for more services than are medically necessary and has warned carriers to control overutilization of medical services. See Brief for Appellees 17-18.

This action by the Secretary is irrelevant. It simply shows that he takes seriously his statutory duty to ensure that only qualifying Part B claims are paid. See 42 U.S.C. §1395y(a) (1976 ed. and Supp. IV); 42 CFR §405.803(b)(1980). It does not establish that the Secretary has sought to discourage payment of Part B claims that do meet Part B requirements. Such an effort would violate Congress' direction. Absent evidence, it cannot be presumed.

would be relevant only if the carriers themselves are biased or interested. We find no basis in the record for reaching such a conclusion.[10] As previously noted, the carriers pay all Part B claims from federal, and not their own, funds. Similarly, the salaries of the hearing officers are paid by the Federal Government. Cf. Marshall v. Jerrico, Inc., supra, at 245, 251, 100 S. Ct., at 1614, 1617. Further, the carriers operate under contracts that require compliance with standards prescribed by the statute and the Secretary. See 42 U.S.C. §§1395u(a)(1)(A)-(B), 1395u(b)(3), and 1395u(b)(4) (1976 ed. and Supp. IV); 42 CFR §§421.200, 421.202, and 421.205(a) (1980). In the absence of proof of

10. Similarly, appellees adduced no evidence to support their assertion that, for reasons of psychology, institutional loyalty, or carrier coercion, hearing officers would be reluctant to differ with carrier determinations. Such assertions require substantiation before they can provide a foundation for invalidating an Act of Congress.

financial interest on the part of the carriers, there is no basis for assuming a derivative bias among their hearing officers.[11]

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11. The District Court's analogy to judicial canons, see n. 4, supra, is not apt. The fact that a hearing officer is or was a carrier employee does not create a risk of partiality analogous to that possibly arising from the professional relationship between a judge and a former partner or associate.

We simply have no reason to doubt that hearing officers will do their best to obey the Secretary's instruction manual:

"The individual selected to act in the capacity of [hearing officer] must not have been involved in any way with the determination in question and neither have advised nor given consultation on any request for payment which is a basis for the hearing. Since the hearings are of a nonadversary nature, be particularly responsive to the needs of unrepresented parties and protect the claimant's rights, even if the claimant is represented by counsel. The parties' interests must be safeguarded to the full extent of their rights; in like manner, the government's interest must be protected.

"The [hearing officer] should conduct the hearing with dignity and exercise necessary control and order . . . . The [hearing officer] must make independent and impartial decisions, write clear and concise statements of facts and law, secure facts from individuals without causing unnecessary friction, and be objective and free of any influence which might affect impartial judgment as to the facts, while being particularly patient with older persons and those with physical or mental impairments.

"'The [hearing officer] must be cognizant of the informal nature of a Part B hearing . . . . The hearing is nonadversary in nature in that neither the carrier nor the Medicare Bureau is in opposition to the party but is interested only in seeing that a proper decision is made.'" App. 22, 31-32, quoting Dept. of HEW, Medicare Part B Carriers Manual, ch. XII, pp. 12-21, 12-29 (1980). Cf. Richardson v. Perales, 402 U.S. 389, 403, 91 S. Ct. 1420, 1428, 28 L. Ed. 2d 842 (1971) ("congressional plan" is that social security administrative system will operate essentially "as an adjudicator and not as an advocate or adversary").

B

[4] Appellees further argued, and the District Court agreed, that due process requires an additional administrative or judicial review by a Government rather than a carrier-appointed hearing officer. Specifically, the District Court ruled that "[e]xisting Part B procedures might remain intact so long as aggrieved beneficiaries would be entitled to appeal carrier appointees' decisions to Part A administrative law judges."[12] 503 F. Supp., at 417. In reaching this conclusion, the District Court applied the familiar test prescribed in Mathews v. Eldridge, 424 U.S., at 335, 96 S. Ct., at 903. See supra, at 1669-1670. We may assume that the District Court was correct in viewing the private interest in Part B payments as "considerable," though "not quite as precious as the right to receive welfare or social security benefits." 503 F. Supp., at 416. We likewise may assume, in considering the third Mathews factor, that the additional cost and inconvenience of providing administrative law judges would not be unduly burdensome.[13]

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12. The claim determination and appeal process available for Part A claims differ from the Part B procedure. See generally 42 CFR part 405, subpart G (1980), as amended, 45 Fed. Reg. 73932-73933 (1980). See also United States v. Erika, Inc., 456 U.S., at 206-207, and nn. 8 and 9, 102 S. Ct., at 1653-1654, and nn. 8 and 9.

13. No authoritative factual findings were made, and perhaps this conclusion would have been difficult to prove. It is known that in 1980 about 158 million Part B claims—up from 124 million in 1978—were filed. Even though the additional review would be available only for disputes in excess of $100, a small percentage of the number of claims would be large in terms of number of cases.

We focus narrowly on the second Mathews factor that considers the risk of erroneous decision and the probable value, if any, of the additional procedure. The District Court's reasoning on this point consisted only of this sentence:

> "In light of [appellees'] undisputed showing that carrier-appointed hearing officers receive little or no formal training and are not required to satisfy any threshold criteria such as having a law degree, it must be assumed that additional safeguards would reduce the risk of erroneous deprivation of Part B benefits." 503 F. Supp., at 416 (footnote omitted).

Again, the record does not support these conclusions. The Secretary has directed carriers to select as a hearing officer "'an attorney or other qualified individual with the ability to conduct formal hearings and with a general understanding of medical matters and terminology. The [hearing officer] must have a thorough knowledge of the Medicare program and the statutory authority and regulations upon which it is based, as well as rulings, policy statements, and general instructions pertinent to the Medicare Bureau.'" App. 22, quoting Dept. of HEW, Medicare Part B Carriers Manual, ch. VII, p. 12-21 (1980) (emphasis added).

The District Court did not identify any specific deficiencies in the Secretary's selection criteria. By definition, a "qualified" individual already possessing "ability" and "thorough knowledge" would not require further training. The court's further general concern that hearing officers "are not required to

satisfy any threshold criteria" overlooks the Secretary's quoted regulation.[14] Moreover, the District Court apparently gave no weight to the qualifications of hearing officers about whom there is information in the record. Their qualifications tend to undermine rather than to support the contention that accuracy of Part B decisionmaking may suffer by reason of carrier appointment of unqualified hearing officers.[15]

"[D]ue Process is flexible and calls for such procedural protections as the particular situation demands." Morrissey v. Brewer, 408 U.S. 471, 481, 92 S. Ct. 2593, 2600, 33 L. Ed. 2d 484 (1972). We have considered appellees' claims in light of the strong presumption in favor of the validity of congressional action and consistently with this Court's recognition of "congressional solicitude for fair

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14. The District Court's opinion may be read as requiring that hearing officers always be attorneys. Our cases, however, make clear that due process does not make such a uniform requirement. See Vitek v. Jones, 445 U.S. 480, 499, 100 S. Ct. 1254, 1266, 63 L. Ed. 2d 552 (1980) (POWELL, J., concurring in part); Parham v. J. R., 442 U.S. 584, 607, 99 S. Ct. 2493, 2506, 61 L. Ed. 2d 101 (1979); Morrissey v. Brewer, 408 U.S. 471, 486, 489, 92 S. Ct. 2593, 2602, 2604, 33 L. Ed. 2d 484 (1972). Cf. Goldberg v. Kelly, 397 U.S. 254, 271, 90 S. Ct. 1011, 1022, 25 L. Ed. 2d 287 (1970). Neither the District Court in its opinion nor the appellees before us make a particularized showing of the additional value of a law degree in the Part B context.

15. The record contains information on nine hearing officers. Two were retired administrative law judges with 15 to 18 years of judging experience, five had extensive experience in medicine or medical insurance, one had been a practicing attorney for 20 years, and one was an attorney with 42 years' experience in the insurance industry who was self-employed as an insurance adjuster. Record, App. to Defendants' Reply to Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Summary Judgment 626, 661-662, 682-685.

procedure. . . ." Califano v. Yamasaki, 442 U.S. 682, 693, 99 S. Ct. 2545, 2553, 61 L. Ed. 2d 176 (1979). Appellees simply have not shown that the procedures prescribed by Congress and the Secretary are not fair or that different or additional procedures would reduce the risk of erroneous deprivation of Part B benefits.

IV

The judgment of the District Court is reversed, and the case is remanded for judgment to be entered for the Secretary.

So ordered.

MEDICARE PROGRAM

Hospital Insurance Benefits (Part A)

Conditions for Medicare Coverage of Surgery to Relieve Obstructions to Vertebral Artery Blood Flow (Vertebral Artery Surgery)

HCFAR 82-3

Purpose: This Ruling restates policy on Medicare coverage of vertebral artery surgery.

Citations: Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)); 42 CFR 405.310(k); 42 CFR 401.108; 47 FR 54939, December 7, 1982.

Pertinent History: Section 1862(a)(1) of the Social Security Act prohibits payment for any expenses incurred for items or services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member". HCFA has interpreted this provision to exclude from Medicare coverage, health care services and items that are not demonstrated by acceptable clinical evidence to be safe and effective. A variety of standards are used to determine whether there is acceptable clinical evidence to warrant a service or procedure. These include approval by the National Institutes of Health, testing by university medical centers, reports published in major medical journals, and general acceptance by the medical community. HCFA's source of medical advice on issues of medical safety and efficacy of items and services is the Public Health Service (PHS).

In 1978, in response to a request by HCFA, PHS advised that five types of vertebral artery surgery can be medically reasonable and necessary, provided that certain conditions are met. This advice was incorporated in instructions

to carriers and intermediaries, effective for services furnished on or after September 1, 1978. (See Part A Intermediary Manual, Chapter II, Coverage of Services, Coverage Issues Appendix, §35-32; Medicare Carriers Manual, Chapter II, Coverage and Limitations, Coverage Issues Appendix, §35-32; and Medicare Hospital Manual, Chapter II, Coverage of Hospital Services, Coverage Issues Appendix, §35-32.)[1]

Since that time, it has come to our attention that these instructions have been challenged in hearings before Administrative Law Judges (ALJs). These hearings provide an opportunity to appeal determinations by a carrier or intermediary that a procedure is not medically reasonable and necessary in a particular case. Because it is not feasible administratively to present expert medical advice at each hearing in which this issue may arise, we are adopting these instructions as a Ruling in order to make them binding on ALJs. This will also assure that HCFA's policy on this issue is applied uniformly.

Held: The following five surgical procedures are performed to relieve obstructions to vertebral artery blood flow—

1. Vertebral artery endarterectomy, a procedure that removes arteriosclerotic plaques that are inside the vertebral artery;
2. Vertebral artery by-pass or resection with anastomosis or graft;
3. Subclavian artery resection, with or without endarterectomy;

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[1]These references were replaced by the Coverage Issues Manual after this Ruling's publication in the Federal Register.

4. Removal of laterally located osteophytes anywhere in the $C_6(C_7)$-C_2 course of the vertebral artery; and

5. Arteriolysis that frees the artery from surrounding tissue, with or without arteriopexy (fixation of the vessel).

These procedures are safe and effective and, as such, are covered Medicare services, only if each of the following conditions is met:

1. Symptoms of vertebral artery obstruction exist. These symptoms include vertigo (sometimes called "dizziness"), vision or speech defects, transient basilar ischemia, stroke, ataxia, and mental confusion. Rotation of the patient's head during physical examination may elicit or accentuate the symptoms.

2. Conditions other than obstructions resulting in blocked vertebral artery blood flow have been considered and ruled out. Other possible causes include orthostatic hypotension, acoustic neuroma, labyrinthitis, diabetes mellitus, various degenerative and systemic disorders of the brain and nervous system, and hypoglycemia-related disorders.

3. There is radiographic evidence of a valid vertebral artery obstruction. If angiograms are used, they should show the aortic arch with the vessels off the arch and the vessels of the head and neck, providing biplane views of the carotid and vertebral vascular system. Serial views are also needed to be able to diagnose subclavian artery obstruction. Obstructions include—

   a. Intravascular obstructions, that is, arteriosclerotic lesions within the vertebral artery or in other arteries;

b. Extravascular obstructions such as—

i. Bony tissue or osteophytes, located laterally in the $C_6(C_7)$-C_2 cervical vertebral area course of the vertebral artery, most commonly at C_5-C_6;

ii. Anatomical variations, that is, anomalous location of the origin of the vertebral artery, and tortuosity and kinks of the vertebral artery; and

iii. Fibrous tissue, that is, connective tissue changed as a result of manipulation of the neck for neck pain or injury associated with bematoma (also called "external bands", "tendinous slings", and "fibrous bands").

Connective tissue along the course of the vertebral artery and vertebral artery tortuosity and kinks only rarely result in symptoms of vertebral artery obstruction.

4. Contraindications to the procedure are not present. For example, coexistent obstructions of multiple cerebral vessels would prevent increased blood flow through the vertebral artery from significantly benefiting the patient.

Further Held: Vertebral artery surgery not meeting the conditions described in this Ruling is excluded from Medicare coverage under the authority of section 1862(a)(1) of the Act.

Effective Date: As explained above, we have previously issued policy in general instructions providing for Medicare coverage of vertebral artery surgery within certain limitations, effective for services furnished on or after September 1, 1978. Since this Ruling is a restatement of policy that has been in effect since that date, this Ruling is effective for services furnished on or after September 1, 1978.

MEDICARE PROGRAM

Provider Reimbursement Review Board

Provider Reimbursement Review Board Decision on the Lack of Jurisdiction

HCFAR 83-1

Summary: This Ruling restates Medicare policy on the limits of the jurisdiction of the Provider Reimbursement Review Board (PRRB).

Citations: 42 U.S.C. 1395oo; 42 CFR 401.108, 405.1835 and 405.1877 (Section 1878 of the Social Security Act); 47 FR 54302, December 2, 1982.

Pertinent History: Section 1395oo of the United States Code (U.S.C.) provides that, under the Medicare program, a provider of services has the right to obtain judicial review of any final decision of the PRRB (related to a cost report or request for hearing filed timely), or of any reversal, affirmance, or modification by the Secretary, by a civil action begun within specified time limits. A provider also has the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the PRRB determines that it is without authority to decide the question. (Again, certain time limits apply.)

The following information is taken from a United States Circuit Court of Appeals decision of April 26, 1982 (Highland District Hospital v. Secretary, 676 F. 2d 230 (6th Cir., 1982)). Highland District Hospital sought judicial review of a PRRB decision that the PRRB lacked jurisdiction to review a determination by Highland's fiscal intermediary, Blue Cross of Southwest Ohio, disallowing certain cost reimbursements requested by Highland.

Highland, the only acute care hospital in Hillsboro, Ohio, owns a three floor building in which it operates a hospital on the first and second floors. During 1974 and 1975, the first and second floors of Highland (approximately 50-60 acute care beds) were certified as a Medicare provider of inpatient medical services. The third floor of the building was operated by Highland as a skilled nursing facility (SNF) which was certified as a separate Medicare provider of extended care services (approximately 30-35 beds).

At various times during 1974 and 1975 all of the first and second floor acute care beds were occupied. As additional acute care patients required admission, Highland set up beds in the hallways on the first and second floors, and either assigned newly admitted patients directly to hallway beds or transferred patients from room beds to hallway beds. Some of the patients in the hallway beds and the room beds were eligible for Medicare.

In 1974, Highland determined there were available beds located in the SNF on the third floor and transferred patients who were in hallway beds on the first and second floors to room beds on the third floor. Highland also reassigned portions of its staff and available hospital services and equipment so that acute care patients treated on the third floor received the same level of care they

previously received on the first and second floors. Thereafter as new acute care patients were admitted, each was assigned to the first available bed in a room whether it was on the first, second or third floor. Vacant beds on the first and second floors were created either by discharge of a patient or by transfer of a patient to a bed on the third floor when acute care was no longer required.

The district court found and the Secretary conceded at oral argument that the level of care provided by Highland to acute care patients was identical, whether a patient was in a room or hallway on the first or second floors or on the third floor.

To qualify for cost reimbursement under Medicare, a hospital or a SNF, as a provider under 42 U.S.C. 1395x(u) must, among other things, enter into an agreement with the Secretary that meets the requirements of 42 U.S.C. 1395cc. Highland Hospital and the Highland SNF entered into a provider agreement with the Secretary and each is a Medicare provider. Part of the agreement binds the provider not to charge a Medicare beneficiary for any services payable under the program except in very limited circumstances, but instead to look only to Medicare for payment. Payment for provider services is based on the lower of the reasonable cost or the customary charge for the services (42 U.S.C. 1395f(b)). The reasonable cost of hospital acute care is generally greater than for the extended care provided by a SNF.

Day-to-day administration of the Medicare program is handled by fiscal intermediaries, which are private nongovernmental entities nominated by a provider or a group of providers. Fiscal intermediaries enter into contracts with the Secretary, under the authority delegated by Congress in 42 U.S.C. 1395h, to

serve as the Secretary's agent for various functions, including auditing provider cost reimbursement requests.

Highland's cost reimbursement requests for 1974 and 1975 included a request for hospital cost reimbursement for the acute care services provided to Medicare patients on the third floor. Those services were provided in beds in which extended care services were normally provided by the Highland SNF. Blue Cross disallowed a part of these requests for each year, though transferring certain staff, operating, and diagnostic facility costs attributable to third floor acute patients to the cost reimbursement request of the Highland SNF. Apparently the balance of the hospital cost reimbursement requests for services provided on the third floor were disallowed by Blue Cross under 42 CFR 405.1803(a) which contains the requirements for an intermediary determination of program reimbursement and notice of the amount. The amount in dispute was found by the district court to aggregate to approximately $200,000.

Blue Cross' determination not to allow Highland cost reimbursement for the acute care services provided to patients treated in the SNF beds was based on Section 3101 of the Medicare Part A Intermediary Manual, which reads:

"When patients requiring extended care services occupy beds in a hospital, they are considered inpatients of the hospital. In such cases, the services furnished in the hospital will not be considered extended care services, and payment may not be made under the program for such services . . . . Such a situation may arise where the hospital is part of an institution having a distinct part SNF (skilled nursing facility), and either there is no bed available in the

distinct part SNF or for any other reason the institution fails to place the patient in an appropriate bed. The same rule applies where the hospital is a separate institution. For the same reason, where patients who require inpatient hospital services occupy beds in a skilled nursing facility, payment cannot be made on their behalf for the services furnished to them in the SNF."

The rationale for this exclusion stems from the fact that generally hospitals may only be reimbursed under Medicare for "inpatient hospital services", 42 U.S.C. 1395d(a)(1), which are defined in 42 U.S.C. 1395x(b) as "services furnished to an inpatient of a hospital . . . by the hospital". The Secretary concluded that inpatients may be treated only on the physical premises of a hospital and thus inpatient hospital services may be furnished only on the physical premises of a hospital. Patients treated in a bed located in a SNF are classified by the Secretary as patients of the SNF rather than as inpatients of the hospital. The hospital thus cannot receive Medicare reimbursement for services provided to those Medicare patients, notwithstanding that the services provided to them are identical to services provided to patients treated on the physical premises of the hospital.

Following Blue Cross' rejection of the Highland cost requests, Blue Cross notified the various patients who had received acute care services on the third floor that payment could not be made to Highland Hospital on their behalf and as a result they were responsible for amounts owed to Highland. Under 42 U.S.C. 1395cc(a)(1)(A), Highland Hospital was free to bill these patients once Blue Cross denied cost reimbursement on their behalf, since a provider agrees not to charge

Medicare beneficiaries only where a payment may be made on their behalf under the program. Presumably the individual patient would be liable only for the difference between the charges for services provided by Highland Hospital and the amount of cost reimbursement, if any, paid to the Highland SNF on his or her behalf.

Highland requested a hearing before the PRRB and argued that patients treated on the third floor of its building were placed in a designated area of the SNF meeting the requirements of a "hospital", as defined in 42 U.S.C. 1395x(e), and that they received services identical to those described in 42 U.S.C. 1395x(b). Highland concluded by stating "we can find no provision in the law which would deny payment for the care given to these patients".

The PRRB dismissed Highland's requests for review. The PRRB ruled that the disallowed costs involved a question of "coverage of inpatient hospital services received in the skilled nursing facility" and stated it could not "take jurisdiction in coverage issues," citing 42 U.S.C. 1395y. The PRRB also held that the annual costs transferred to the SNF were in aggregate less than the $10,000 jurisdictional minimum for PRRB review, 42 U.S.C. 1395oo(a)(2).

Highland then filed an action seeking judicial review under 42 U.S.C. 1395oo(f). The district court dismissed the complaint on motion of the Secretary. In its memorandum opinion, the district court rejected the Secretary's argument that the PRRB's dismissal of Highland's appeal request was not a "final determination" by the PRRB permitting Highland to invoke 42 U.S.C. 1395oo(f). Cleveland Memorial Hospital v. Califano, 444 F. Supp. 125 (E.D.N.C.1978). The district judge concluded, after quoting extensively from

Mount Sinai Hospital of Greater Miami, Inc. v. Weinberger, 517 F. 2d 329, 334-336 (5th Cir. 1975), cert. denied, 425 U.S. 935 (1976), that (1) the PRRB correctly determined a question of coverage was involved and that therefore it was without jurisdiction; and (2) Highland had not exhausted the administrative remedies available under 42 U.S.C. 1395ff(c), from which judicial review would be available.

Highland then appealed to the circuit court and argued that the district court erred in ruling that the PRRB lacked jurisdiction to review the determinations by Blue Cross. The Secretary responded that the PRRB and the district court correctly held that Blue Cross' determination was one of "coverage," thus precluding PRRB review. According to the Secretary, administrative and judicial review was available only to the individual beneficiaries under 42 U.S.C. 1395ff(b), or in the alternative, to Highland only under 42 CFR 405.710, 405.720 and 405.730 rather than through the PRRB under 42 U.S.C. 1395oo(a) and (f) and 42 CFR 405.1835 and 405.1877.

The review procedure Highland sought to invoke is set forth in 42 U.S.C. 1395oo and more fully described in regulations at 42 CFR 405.1835 and 405.1877. Section 1395oo(a) of the U.S.C. provides in part:

"Any provider of services which has filed a required cost report within the time specified in regulation may obtain a hearing with respect to such cost

report by a Provider Reimbursement Review Board . . . if—

(1) such provider—

(A) is dissatisfied with a final determination of the organization serving as its fiscal intermediary pursuant to section 1395h of this title as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this subchapter for the period covered by such report . . .

(2) the amount in controversy is $10,000 or more, and

(3) such provider files a request for a hearing within 180 days after notice of the intermediary's final determination under paragraph (1)(A) . . . ."

Administrative review by the Secretary on his own motion and judicial review are authorized by 42 U.S.C. 1395oo(f); however, a provider has no right to demand administrative review (42 CFR 405.1875).

Section 1395oo(f) of the U.S.C. reads in part:

"(1) A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board's decision, reverses, affirms, or modifies the Board's decision. Providers shall have the right to obtain judicial review of any final decision of the Board or of any reversal, affirmance, or modification by the Secretary by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is

received .... Such action shall be brought in the district court of the United States for the judicial district in which the provider is located ...."

The scope of both administrative and judicial review is limited by 42 U.S.C. 1395oo(g):

"The finding of a fiscal intermediary that no payment may be made under this subchapter for any expenses incurred for items or services furnished to an individual because such items or services are listed in §1395y of this title shall not be reviewed by the Board, or by any court pursuant to any action brought under subsection (f) of this section."

The jurisdiction of the PRRB is thus contained in 42 U.S.C. 1395oo(a) as restricted by 42 U.S.C. 1395oo(g). The PRRB is empowered to decide questions relating to its own jurisdiction to grant a hearing, including determining issues of timeliness and amount in controversy (42 CFR 405.1873(a)). It is clear, however, that a determination by a fiscal intermediary that Medicare payment is not available for items and services because they are excluded under 42 U.S.C. 1395y is outside the jurisdiction of the PRRB (42 CFR 405.1873(b)).

Both the PRRB and the district court agreed with the Secretary's position that Highland's appeal from the denial of its reimbursement requests could not be heard by the PRRB because a question of "coverage" was involved. Yet neither the statute nor the regulations employ or define the term "coverage" in delineating PRRB jurisdiction. The legislative history, while making it clear that questions of coverage are outside that PRRB review process, does not define what is or is not a coverage question.

The term "coverage" in this context is used, apparently for the only time, in the Report of the House Ways and Means Committee on the Social Security Amendments of 1972, Pub. L. 92-603, 86 Stat. 1329 (1972):

"Provider reimbursement review board.—Under present law there is no specific provision for an appeal by a provider of services of a fiscal intermediary's final reasonable cost determination. Although the HEW has developed administrative procedures to assist providers and intermediaries to reach reasonable and mutually satisfactory settlements of disputed reimbursement items, your committee believes that it is desirable to prescribe in law a specific procedure for settling disputed final determinations applying to the amount of program reimbursement. This procedure would not apply to questions of coverage or disputes involving individual beneficiary claims." H.R. Rep. No. 231, 92nd Cong., 2nd Sess., (1972), reprinted in (1972) U.S. Code Cong. and Ad. News 4989, 5094.

In Mount Sinai Hospital of Greater Miami, Inc. v. Weinberger, supra, the Fifth Circuit defined "coverage" questions as those issues framed by 42 U.S.C. 1395d and 1395y. Section 1395d(a)(1)-(3) of the U.S.C. defined the hospital insurance benefits covered by Medicare, consisting of inpatient hospital services, extended care services and home health services. Section 1395y of the U.S.C. defines exclusions from the general definition of the scope of benefits in 42 U.S.C. 1395d. Under this analysis, a service is "covered" if it falls within the scope of benefits defined by 42 U.S.C. 1395d and is not excluded by 42 U.S.C. 1395y. A "coverage" issue thus is involved where the question is whether services provided fall within the scope of benefits defined by 42 U.S.C. 1395d or are excluded by 42 U.S.C. 1395y.

In this case, Blue Cross determined that Highland was not entitled to cost reimbursement for acute care services provided in the SNF because in its view those services were not inpatient services under 42 U.S.C. 1395d. "Inpatient hospital services" are defined in 42 U.S.C. 1395x(b) as various listed "items and services furnished to an inpatient of a hospital . . . by the hospital". As noted earlier, the Secretary does not regard a patient in a SNF bed as a patient of the hospital, but rather as a patient of the SNF. Any service provided to such a patient thus cannot by definition qualify as "inpatient hospital services" under 42 U.S.C. 1395d and 1395x(b) because they were not provided to an inpatient of the hospital, even though an identical service provided to a patient in an acute care bed in the hospital would qualify.

Highland held the position that the portion of the SNF into which acute care patients were placed constituted a "hospital" under 42 U.S.C. 1395x(e) so that patients treated there were inpatients of a hospital and thus received inpatient hospital services. At its core, the dispute is whether acute care services provided to persons on the premises of a non-hospital provider qualify as "inpatient hospital services" under 42 U.S.C. 1395d. Clearly a question of 42 U.S.C. 1395d "coverage" is involved.

In the opinion of the circuit court, the PRRB's determination that it lacked jurisdiction and the district court's holding to that effect were correct.

The circuit court's conclusion that Highland is not entitled to PRRB review of Blue Cross' disallowance of cost reimbursement for acute care services provided in the SNF does not leave Highland without the opportunity to recover its cost. The provider agreement Highland entered into with the Secretary obligated it not to charge Medicare patients for any items or services for which

such individual is entitled to have payment made under 42 U.S.C. 1395cc(a)(1)(A), but instead to look only to the government for payment. Once Blue Cross determined payment could not be made to Highland on behalf of Medicare acute care patients treated in the SNF on the third floor, Blue Cross notified those patients that payment would not be provided by Medicare.

Highland was then no longer bound by its agreement not to charge these patients for acute care services provided in the SNF and was free to do so. As Medicare beneficiaries, the patients had available to them procedures for administrative and judicial review of the fiscal intermediary's determination of noncoverage (42 U.S.C. 1395ff(b)). Each beneficiary could demand reconsideration under 42 CFR 405.710(a), a hearing before an administrative law judge under 42 CFR 405.720, Appeals Council review under 42 CFR 405.724 and judicial review under 42 CFR 405.730 as authorized by 42 U.S.C. 1395ff(b). The scope of administrative review available to beneficiaries on reconsideration under 42 CFR 405.710(a) of initial determinations under 42 CFR 405.704(a), is much broader than that available to providers under 42 CFR 405.710(b) of initial determinations under 42 CFR 405.704(b).[1] Specifically, issues of "coverage" and "any other issue having a present or potential effect on the amount of benefits to be paid" are included (42 CFR 405.704(a)(1)(13)).

Since each patient was contractually liable to Highland for the services provided, each had the incentive to invoke the administrative and judicial avenues of review available. The decision by Blue Cross was in no sense

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[1] Current 42 CFR 405.710 contains references to the paragraphs of section 405.704 as they existed prior to revision on May 1, 1981. The references to the paragraphs of 42 CFR 405.704 presented in the text are the references as they existed prior to the revision.

unreviewable; the review proceedings simply had to be invoked by the putative beneficiaries rather than by Highland as the provider.

The intent of the Medicare program, in a general sense, is to provide assistance to the elderly and disabled in meeting medical costs and to provide a coordinated approach for health insurance and medical care for beneficiaries to assure the availability of medical care. Cost reimbursement to providers is but a means of accomplishing those goals, allowing the provider to rely on the Federal government rather than the patient for payment. While a provider such as Highland may with good reason prefer to look to the Federal government rather than to an individual, it has no independent right to cost reimbursement or to choose its debtor; it must follow the review procedures set forth in the statute and regulations. In this instance, Highland had to look to its patients for payment and allow them the opportunity to pursue review of Blue Cross' determination.

Accordingly, the determination by Blue Cross that Medicare payment could not be made on behalf of Medicare patients who received acute care services in the Highland SNF involved a question of coverage under 42 U.S.C. 1395d. Thus, the PRRB was without jurisdiction to hear Highland's appeal requests. The judgment of the district court was AFFIRMED by the circuit court.

Ruling: The PRRB lacks jurisdiction to review determinations based on coverage questions.

Effective Date: December 2, 1982.

MEDICARE PROGRAM

Hospital Insurance Benefits (Part A)

Criteria for Defining Skilled Nursing Facility Under Section 1861(j)(1) of the Social Security Act

HCFAR 83-2

Purpose: This Ruling provides public notice of the criteria the Secretary has established for defining "skilled nursing facility" under section 1861(j)(1) of the Social Security Act (the Act).

Citations: Sections 1812 and 1861 of the Social Security Act (42 U.S.C. 1395d and 1395x); 42 CFR 401.108; 47 FR 54551, December 3, 1982.

Pertinent History: Under the Hospital Insurance Program (Medicare-Part A), payment for covered inpatient hospital and skilled nursing facility (SNF) services is available for a limited number of days during each benefit period or "spell of illness". Once a beneficiary has exhausted that allotted number of days (150 days for inpatient hospital care[1] and 100 days for SNF care), no further Part A program payment is available for those services until the beneficiary ends that "spell of illness" and begins a new one (Section 1812(a) of the Act, 42 U.S.C. 1395d(a)). A patient's "spell of illness" begins on the day he or she is furnished hospital or SNF services and ends when he or she has not been an inpatient of a hospital or SNF for 60 consecutive days (Section 1861(a) of the Act, 42 U.S.C. 1395x(a)).

The material following section 1861(j)(15) of the Act (42 U.S.C. 1395x(j)(15)) specifies that for purposes of determining when a "spell of illness"

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[1] A beneficiary may receive up to 90 days of inpatient hospital care per spell of illness and has an additional 60 days of lifetime reserve benefits upon which to draw.

ends under section 1861(a), a SNF is defined by section 1861(j)(1) of the Act (42 U.S.C. 1395x(j)(1)). This latter provision defines a SNF as a facility which

"(1) is primarily engaged in providing to inpatients (A) skilled nursing care and related services for patients who require medical or nursing care, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons."

Thus, a beneficiary who continuously resides in a nursing home meeting this definition is considered an inpatient of a SNF under section 1861(a), and cannot close out his or her "spell of illness" for purposes of receiving renewed benefits.

HCFA developed criteria early in the program which clarify their definition of a skilled nursing facility. These criteria are included in section 3412 of the State Operations Manual. The HCFA Ruling published in this notice restates the criteria set forth in that manual.

Criteria for Defining Skilled Nursing Facility Under Section 1861(j)(1) of the Social Security Act

Ruling: An institution meets the section 1861(j)(1) definition of "skilled nursing or rehabilitation facility" only if all the following criteria are met.

A. Nursing Services.—Nursing services are provided under the direction or supervision of one or more registered nurses or licensed practical or vocational nurses without regard to whether they are "waived." This condition will be considered met even if the nurse is also the administrator of the facility or is employed on a part-time basis.

B. 24-Hour Nursing Services.—There are nursing personnel on duty 24 hours a day. The term "nursing personnel" includes registered nurses, licensed

practical or vocational nurses without regard to whether they are "waived" or not, practical nurses, student nurses, nursing aides, and orderlies.

C. Nurse-Bed Ratio.—The number of full-time equivalent nursing personnel to the number of beds is not less than an average ratio of 1 to 15 per shift.

Note.—Generally, there will be a close equivalency between the number of beds and average number of patients in an institution. Where the circumstances indicate a significant discrepancy in these factors, the ratio of nurses to the average patient census should be used in determining section 1861(j)(1) status.

A facility which has three 8-hour shifts would have to have a minimum of the equivalent of three full-time nursing personnel during a 24-hour period for each 15 beds. It is not necessary that the 1 to 15 ratio be maintained for each shift, but the average of all shifts must be at least 1 to 15. Nursing personnel include all those persons listed in paragraph B above. In determining the ratio, nurses who are also administrators should be counted as nursing personnel.

D. Other Services.—Bed and board are provided to inpatients in connection with the furnishing of nursing care, plus one or more medically related health services such as physicians' services, physical, occupational or speech therapy, diagnostic and laboratory services, and administration of medication. (Social, diversional, or recreational services provided by the institution would not be considered medically related health services.)

Effective Date: December 3, 1982.

MEDICARE PROGRAM

Hospital Insurance Benefits (Part A)

Revised Criteria for Defining a Skilled Nursing Facility When Determining A Beneficiary's Spell of Illness Status

HCFAR 83-3

Purpose: This Ruling provides public notice of the revised criteria that HCFA has established for defining a skilled nursing facility (SNF) under section 1861(j)(1) of the Social Security Act (the Act) when determining a beneficiary's spell of illness status.

Citations: Section 1812 and 1861 of the Social Security Act (42 U.S.C. 1395d and 1395x); 42 CFR 401.108; 49 FR 10710, March 22, 1984.

Pertinent History: Under the Hospital Insurance Program (Medicare—Part A), payment for covered inpatient hospital and skilled nursing facility services is available for a limited number of days during each benefit period or spell of illness. Once a beneficiary has exhausted that allotted number of days (90 days for inpatient hospital care plus 60 lifetime reserve days and 100 days for SNF care), no further Part A program payment is available for those services until the beneficiary ends that spell of illness and begins a new one (Section 1812(a) of the Act, 42 U.S.C. 1395d(a)). A patient's spell of illness begins on the day he or she is furnished hospital or SNF services and ends when he or she has not been an inpatient of a hospital or SNF for 60 consecutive days (Section 1861(a) of the Act, 42 U.S.C. 1395x(a)).

The material following section 1861(j)(15) of the Act (42 U.S.C. 1395x(j)(15)) specifies that for purposes of determining when a spell of illness

ends under section 1861(a), an SNF is defined by section 1861(j)(1) of the Act (42 U.S.C. 1395x(j)(1)). This latter provision defines an SNF as a facility that:

> "(1) Is primarily engaged in providing to inpatients (A) skilled nursing care and related services for patients who require medical or nursing care, or (B) rehabilitation services, for the rehabilitation of injured, disabled, or sick persons."

Thus, while a beneficiary is an inpatient of a nursing home which meets this definition, the beneficiary is considered an inpatient of an SNF under section 1861(a) of the Act and cannot terminate his or her spell of illness for purposes of receiving renewed benefits.

We developed criteria early in the program that clarified the section 1861(j)(1) definition of a skilled nursing facility. These criteria are included in section 3412 of the State Operations Manual and in a HCFA Ruling (HCFAR 83-2) published in the Federal Register on December 3, 1982 (47 FR 54551). For determinations made prior to October 17, 1983, these criteria defined those SNFs where a stay could either prolong a spell of illness or constitute a patient's being in his "home" for purposes of the DME and home health benefits.

As a result of the recent court order in Kron v. Heckler, Civil Action No. 80-1332 (E.D. La., October 17, 1983), we instructed all fiscal intermediaries to start using a new set of criteria for defining section 1861(j)(1) facilities for spell of illness purposes. The new criteria, effective as of October 17, 1983 (the date the Kron judgment was entered), retain the previous section 1861(j)(1) criteria elements, but also provide that a section 1861(j)(1) SNF, for purposes of

prolonging a Medicare spell of illness, cannot include a facility or part of a facility that is licensed by the State solely as an intermediate care facility (ICF). This Ruling utilizes the elements of the definition of spell of illness that were contained in our instruction to fiscal intermediaries and also contains further clarifying language. The Ruling is applicable to spell of illness determinations made on or after October 17, 1983 and applies only to use of the "spell of illness" concept in the context of hospital or skilled nursing facility services, coverage, and reimbursement under Medicare. HCFAR 83-2 (47 FR 54551, December 3, 1982) is modified to the extent necessary to conform to this Ruling.

Criteria for Defining a Skilled Nursing Facility Under Section 1861(j)(1) of the Social Security Act When Determining a Beneficiary's Spell of Illness Status

Ruling: An institution meets the section 1861(j)(1) definition of skilled nursing or rehabilitation facility for purposes of prolonging a spell of illness under sections 1812(a) and 1861(a)(2) of the Social Security Act only if all the following criteria are met.

A. Nursing Services.—Nursing services are provided under the direction or supervision of one or more registered nurses or licensed practical or vocational nurses without regard to whether they are "waived." This condition will be considered met even if the nurse is also the administrator of the facility or is employed on a part-time basis.

B. 24-Hour Nursing Services.—There are nursing personnel on duty 24 hours a day. The term "nursing personnel" includes registered nurses, licensed practical or vocational nurses without regard to whether they are "waived" or not, practical nurses, student nurses, nursing aides, and orderlies.

C. Nurse-Bed Ratio.—The number of full-time equivalent nursing personnel to the number of beds is not less than an average ratio of 1 to 15 per shift.

Note.—Generally, there will be a close equivalency between the number of beds and average number of patients in an institution. When the circumstances indicate a significant discrepancy in these factors, the ratio of nurses to the average patient census should be used in determining section 1861(j)(1) status.

A facility which has three 8-hour shifts would have to have a minimum of the equivalent of three full-time nursing personnel during a 24-hour period for each 15 beds. It is not necessary that the 1 to 15 ratio be maintained for each shift, but the average of all shifts must be at least 1 to 15. Nursing personnel include all those persons listed in paragraph B above. In determining the ratio, nurses who are also administrators should be counted as nursing personnel.

D. Other Services.—Bed and board are provided to inpatients in connection with the furnishing of nursing care, plus one or more medically related health services such as physicians' services, physical, occupational or speech therapy, diagnostic and laboratory services, and administration of medication. (Social, diversional, or recreational services provided by the institution would not be considered medically related health services.)

E. Not Solely an Intermediate Care Facility.—The facility or part of a facility which is being classified is not—

1. Certified solely as an intermediate care facility, consistent with 42 CFR Part 442, Subpart E; or
2. Licensed by the State solely at a level or levels at or below the intermediate care facility (or a comparable) level.

Effective Date: March 22, 1984.

MEDICARE PROGRAM

Provider Reimbursement Review Board

Provider Reimbursement Review Board Jurisdiction Over Appeals from Estimations of and Modifications to Base Year Costs Under the Prospective Payment System

HCFAR 84-1

Purpose: This Ruling provides public notice of the interpretation by HCFA of the regulations at 42 CFR 405.474(b)[1] and 42 CFR 405.1801 et seq. which implement the reviewing authority of the PRRB under section 1878(a)(1)(A) of the Social Security Act, 42 U.S.C. 1395oo(a)(1)(A).

Citations: Section 1878 of the Social Security Act (42 U.S.C. 1395oo(a)) and 42 CFR 401.108 and 405.1801 et seq.; 49 FR 22413, May 29, 1984.

Pertinent History: During the transition period for introduction of the PPS, the payment amount made to hospitals for each discharge consists of two parts. The "Federal portion" is a percentage of the product determined by multiplying the weighting for the applicable diagnosis related group (DRG) by the appropriate standardized amount. The standardized amounts are based on the historical average costs of all hospitals in a designated grouping, i.e., throughout the nation, within a particular census division and within designated urban or rural areas. The other part of the payment for each discharge, the "hospital-specific portion" is determined in the same way, except that the DRG weighting is multiplied by an amount reflecting the historical average costs of the particular hospital, rather than of a group of hospitals.

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[1] 42 CFR 405.474(b) was redesignated May 29, 1985, as 42 CFR 412.71 through 412.73.

The cost base for determining the hospital-specific portion is determined by using each hospital's cost per discharge (after adjustment for the complexity of its case mix) during the hospital's 12-month cost reporting period ending on or after September 30, 1982, and before September 30, 1983 (42 CFR 405.474(b)(1)).[2] Costs incurred during this base year are determined by the intermediaries in accordance with usual Medicare rules. Costs that Medicare does not allow are excluded by the intermediaries, and are neither the basis for reimbursement for the base year nor the basis for determining a hospital's historical costs in connection with the PPS hospital-specific portion.

After the intermediary determines a hospital's base year costs, the intermediary adjusts the costs in certain respects for the purpose of adapting the costs to use in the prospective payment system. These modifications do not affect a hospital's reimbursement for the base year, but only the amount of its hospital-specific payment rate under PPS. The potential modifications involve nursing differential costs, direct medical education costs, capital-related costs, kidney acquisition costs, malpractice insurance costs, services paid under Medicare Part B during the base year but covered by the prospective payment amount, FICA taxes to be paid during the PPS period but not paid during base period, costs that were incurred for the purpose of increasing base year costs or

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[2] 42 CFR 405.474(b)(1) was redesignated May 29, 1985, as 42 CFR 412.71(a).

revenues that have the effect of distorting base year costs as an appropriate basis for computing the hospital-specific rate, and higher costs that result from changes in hospital accounting principles initiated in the base year (42 CFR 405.474(b)).[3]

The intermediary's estimation of a hospital's base year costs and modifications thereto are reported to the hospital on HCFA Form 1007 prior to the beginning of its first cost reporting period under PPS. Ordinarily the estimation of base year costs appearing on this form will be identical to the determination of the base year costs in the NPR for the base year.

Questions have been raised as to the time at which the PRRB has jurisdiction to review the intermediaries' calculation of base year costs and the modifications thereto described above. In particular, the issue is whether the intermediary's estimation of base year costs and modifications thereto is reviewable at the time that this calculation is made and provided to each hospital prior to its becoming subject to PPS.

Actions that are reviewable by the PRRB are defined by statute and HCFA regulations. Section 1878 of the Social Security Act, 42 U.S.C. 1395oo, allows a hospital subject to PPS to appeal to the PRRB if it "has submitted such reports within such time as the Secretary may require in order to make payment" and is dissatisfied with a "final determination of the Secretary" as to the amount of payment under the PPS statutory provisions. HCFA's regulations make clear

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[3]See Footnote 1.

that the determination triggering the right of hospitals under PPS to PRRB review "includes a determination of the total amount of payment due the hospital under that system for the hospital's cost reporting period covered by the determination" (42 CFR 405.1801(a)(2)-(3)). The regulations thus specify that issues related to payment amounts under PPS may not be appealed to the PRRB until the hospital seeking appeal has received its notice of amount of program reimbursement (NPR) for the PPS cost reporting period involved. Only the NPR determines the "total amount of payment due the hospital," as required by the regulations for PRRB review. (The regulations state that the appealable intermediary determination "includes" the determination of total PPS payments because the determination will also include reimbursement for capital costs and other items outside PPS.)

Moreover, in commenting on the interim PPS regulations published in the Federal Register on September 1, 1983 (48 FR 39751-39890), at least one commenter urged that the regulations be "clarified" to allow intermediary determinations regarding base year costs to be appealed to the PRRB immediately. The response to that and related comments in the preamble to the final regulations published January 3, 1984 (49 FR 279), stated:

> "Disputes that arise concerning prospective payments will be resolved under the administrative and judicial review procedures established in section 1878 of the Act and the Medicare regulations at 42 CFR Part 405, Subpart R. Under these procedures, a provider that is dissatisfied with the intermediary determination of the total amount of the program

reimbursement due for a cost reimbursement period (as contained in a "Notice of Amount of Program Reimbursement" issued after the close of the period) may request a hearing. . . ."

Thus, the preamble also makes clear that the PRRB has jurisdiction to hear issues with respect to PPS payment amounts only after an NPR has been issued following conclusion of the applicable cost reporting period.

Insofar as a hospital seeks PRRB review of the intermediary's determination of the hospital's costs during the base year cost reporting period itself, however, the hospital may appeal to the PRRB following receipt of the NPR applicable to such year. If the hospital is successful in its appeal, its reimbursement for the base year will be adjusted accordingly and the hospital's hospital-specific payment rate will be adjusted beginning with the first day of the hospital's first cost reporting period on or after the hospital's successful appeal. Thus, as a practical matter, initiation of PRRB review of an intermediary's determination for which an NPR is issued for the cost reporting period which serves as the base year will have the effect of appealing an intermediary's estimation of base year costs (but not including modifications thereto) before the conclusion of a hospital's first cost reporting period under PPS.

If a hospital seeks PRRB review of an intermediary's modifications to its base year costs, which were made by the intermediary not to affect base year reimbursement but for the purpose of establishing a hospital's PPS hospital-specific payment rate, appeal may not be sought immediately. Instead, as

explained above, the PRRB lacks jurisdiction to review such actions until the hospital has received its NPR for its first PPS cost reporting period. Similarly, the PRRB lacks jurisdiction to review the estimation of a hospital's base year costs as stated on the HCFA Form 1007.

The prohibition on appealing issues related to PPS until after issuance of the NPR serves the substantial purpose of preventing piecemeal litigation. In the event that a hospital successfully appeals the modifications to its base year costs made by the intermediary for purposes of PPS, the results of the appeal will be retroactive to the time of intermediary's action (42 CFR 405.474(b)(2)(iv)).

Ruling: It is HCFA's Ruling that an intermediary's estimation of a hospital's base year costs and modifications thereto, made for purposes of determining the hospital-specific rate under PPS (HCFA Form 1007), is neither a final determination of program reimbursement nor a notice of the amount of program reimbursement as required by the statute and regulations. Accordingly, the PRRB has jurisdiction to review an intermediary's modifications to base year costs made for purposes of implementing the prospective payment system, or the estimate of those costs as stated on HCFA Form 1007, only after an NPR has been issued for the hospital's first cost reporting period under the prospective payment system.

Effective Date: May 29, 1984

MEDICARE PROGRAM

Hospital Insurance Benefits (Part A)

Exclusion of Cytotoxic Leukocyte Testing from Medicare Coverage

HCFAR 85-1

Purpose: This Ruling announces HCFA's decision to exclude Medicare coverage of cytotoxic leukocyte testing for food allergies.

Citations: Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)); 42 CFR 401.108; 42 CFR 405.310(k); 50 FR 27691, July 5, 1985.

Pertinent History: We published a notice in the Federal Register on August 19, 1983 (48 FR 37716) proposing to exclude certain food allergy testing and treatment procedures from Medicare coverage. We received more than 19,000 comments on the notice; approximately 170 specifically mentioned cytotoxic leukocyte testing. These commenters oppose the elimination of Medicare coverage for this procedure. Their opposition is testimonial in nature and included no scientific studies supporting the efficacy of cytotoxic leukocyte testing for food allergies. Further, the Food and Drug Administration (on page 2 of its Compliance Policy Guide 7124.27 dated 3/19/85) states that the consensus of scientific opinion is that the cytotoxic test is unreliable as a diagnostic tool and is not generally recognized by qualified experts as effective. Therefore, based on all information available to us, we have determined that cytotoxic leukocyte testing lacks an acceptable scientific rationale, specificity, sensitivity, and evidence of clinical effectiveness.

Ruling: Cytotoxic leukocyte testing for food allergies is excluded from Medicare coverage because available evidence does not show that these tests are safe and effective.

Effective Date: August 5, 1985.

Cross-References: Identical instructions can be found in the following HCFA publications: Part A Intermediary Manual (HCFA Pub. 13-3), Chapter II, Coverage Issues Appendix, section 50-2; Medicare Carriers Manual (HCFA Pub. 14-3), Chapter II, Coverage Issues Appendix, section 50-2; Hospital Manual (HCFA Pub. 10), Coverage Issues Appendix, section 50-2.[1]

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[1] These instructions were replaced by the Coverage Issues Manual after this Ruling's publication in the Federal Register.

MEDICARE PROGRAM

Hospital Insurance Benefits Program (Part A)

Criteria for Medicare Coverage of Inpatient Hospital Rehabilitation Services

HCFAR 85-2

Purpose: This Ruling provides further public notice of HCFA's criteria for Medicare coverage of inpatient hospital rehabilitation services.

Citations: Sections 1812, 1814, 1861 and 1862 of the Social Security Act (the Act) (42 U.S.C. 1395d, 1395f, 1395x, and 1395y); 42 CFR 401.108 and 42 CFR 405.310(k); 50 FR 31040, July 31, 1985.

Pertinent History: Under the Medicare program, there has always been a statutory exclusion of payment for services that ". . . are not reasonable and necessary for the diagnosis or treatment of illness or injury . . ." (section 1862(a)(1) of the Act). It is this authority, taken in conjunction with the descriptions of the various benefits, that the program uses to deny payment when services required by a patient could have been appropriately provided in an inpatient setting which is less intensive than the hospital setting or in an outpatient setting. (See also section 1154 of the Act.)

Rehabilitation care is furnished in a variety of settings ranging from the inpatient hospital setting, through the skilled nursing facility setting, to various outpatient settings such as, for example, home health care and outpatient physical therapy. To determine whether inpatient hospital care is necessary for the provision of rehabilitation services, it is first necessary to determine what rehabilitation services the patient requires and then to determine whether they need to be provided in the inpatient hospital setting.

Typically, a preadmission screening is done before a patient is admitted to a rehabilitation hospital. This screening is a preliminary review of the patient's condition and previous medical record to determine if the patient is likely to benefit significantly from an intensive hospital program or extensive inpatient assessment. Further inpatient assessment of a patient's potential for rehabilitation may be done if it is reasonable and necessary to perform the assessment in the hospital.

We developed criteria early in the program to assist medical review entities in applying the basic "reasonable and necessary" test to inpatient rehabilitation services under Part A. These criteria are used to help a medical review entity determine whether rehabilitative care in a hospital, rather than in a SNF or on an outpatient basis, is reasonable and necessary. The criteria have been revised from time to time to respond to new questions of interpretation which have arisen. Section 3101.11 of the Intermediary Manual contains the current version of these criteria. The HCFA Ruling published in this notice restates the criteria set forth in that manual.

Ruling

A. General.—Physicians generally agree on the circumstances that justify a medical or surgical patient's hospitalization, and, in some cases, an admission to a rehabilitation hospital or to the rehabilitation service of a short-term hospital can be justified on essentially the same medical or surgical grounds. In other cases, however, a patient's medical or surgical needs alone may not warrant inpatient hospital care, but hospitalization

may nevertheless be necessary because of the patient's need for rehabilitative services.

A hospital level of care is required by a patient needing rehabilitative services if that patient needs a relatively intense rehabilitation program that requires a multidisciplinary coordinated team approach to upgrade his ability to function. There are two basic requirements which must be met for inpatient hospital stays for rehabilitation care to be covered:

1. The services must be reasonable and necessary (in terms of efficacy, duration, frequency, and amount) for the treatment of the patient's condition; and
2. It must be reasonable and necessary to furnish the care on an inpatient hospital basis, rather than in a less intensive facility, such as a SNF, or on an outpatient basis.

B. Preadmission Screening.—Before a patient is admitted to a rehabilitation hospital for treatment, a preadmission screening is normally done. This screening is a preliminary review of the patient's condition and previous medical record to determine if the patient is likely to benefit significantly from an intensive hospital program or extensive inpatient assessment.

While preadmission screening is a standard practice in most rehabilitation hospitals and may provide useful information for claims review purposes, the absence of a preadmission screening in a particular case should not be the sole reason for denying a claim. However, in a case where an inpatient assessment showed that a patient clearly was not

a good candidate for an inpatient hospital program, then the presence or absence of preadmission screening information would be important in determining whether the inpatient assessment itself was reasonable and necessary. If preadmission screening information indicated that the patient had the potential for benefiting from an inpatient hospital program, a period of inpatient assessment could be covered up to the point where it was determined that inpatient hospital rehabilitation was not appropriate, since preadmission screening cannot be expected to eliminate all unsuitable candidates.

C. Inpatient Assessment of an Individual's Status and Potential for Rehabilitation.

1. General.—Coverage is available for inpatient assessment of a patient's potential for benefiting from an intensive coordinated rehabilitation program only if it was reasonable and necessary to perform the assessment in the hospital. This determination should be made on the basis of information available in the patient's medical record. It is important to note that the assessment process is not merely a paperwork review, but rather an onsite professional review of the patient's condition by the necessary disciplines. Inpatient assessments conducted by a rehabilitation team through examination of the patient usually require between 3 to 10 calendar days, but on occasion may require more. This 3-10 day period is often one where the patient is receiving therapies rather than simple screening assessments. Where more than 10 days are required, the case should be carefully reviewed to ensure that such additional time was

necessary. An inpatient assessment may be covered even if the assessment subsequently indicates that a patient is not suitable for an intensive inpatient hospital rehabilitation program, if the patient's condition on admission was such that an extensive inpatient assessment was considered reasonable and necessary for a final decision to be made on a patient's actual rehabilitation potential. Where the initial assessment has resulted in a conclusion that the individual is a poor candidate for rehabilitation care, coverage for further inpatient hospital care is limited to a reasonable number of days needed to permit appropriate placement of the patient.

The fact that an individual received therapy prior to admission to a hospital for a rehabilitation program would not necessarily mean that the initial assessment period was not reasonable and necessary. However, if during a previous hospital stay an individual completed such a program for essentially the same condition for which inpatient hospital care is now being provided, the assessment period could be covered only if:

(1) Some intervening circumstance rendered such an assessment reasonable and necessary; or

(2) The subsequent admission is to an institution utilizing techniques or technology not previously available or not available in the first institution.

2. Specific examples:

a. After an inpatient hospital stay for rehabilitation care which resulted in little improvement in the patient's condition, an

individual who undergoes surgery for severe contractures as a result of arthritis may require a reassessment of his rehabilitation potential in light of the surgery.

b. The fact that an individual has some degree of mental impairment would not per se be a basis for concluding that a multidisciplinary team evaluation is not warranted. Many individuals who have had CVAs[1] suffer both mental and physical impairments. The mental impairment often results in a limited attention span and reduced comprehension with a resultant problem in communication. With an intensive rehabilitation program, it is sometimes possible to correct or significantly alleviate both the mental and physical problems.

c. Absent other complicating medical problems, the type of rehabilitation program normally required by a patient with a fractured hip during or after the nonweightbearing period or a patient with a healed ankle fracture would not require an inpatient hospital stay for rehabilitation care. Accordingly, an inpatient assessment would not be warranted in such cases. On the other hand, an individual who has had a CVA which has left the individual significantly dependent in the activities of daily living (even after physical therapy in a different setting) might be a good candidate for a more extensive inpatient assessment

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[1] Cerebrovascular accidents

if the patient has potential for rehabilitation and his needs are not primarily of a custodial nature.

D. Inpatient Rehabilitation Hospital Care.—Rehabilitative care in a hospital, rather than in a SNF or on an outpatient basis, is reasonable and necessary for a patient who requires a more coordinated, intensive program of multiple services than is generally found out of a hospital. A patient who has one or more conditions requiring intensive and multidisciplinary rehabilitation care, or who has a medical complication in addition to his primary condition, so that the continuing availability of a physician is required to ensure safe and effective treatment, would probably require a hospital level of rehabilitation care. A patient in need of rehabilitation on an inpatient hospital basis requires all of the following:

1. Close medical supervision by a physician with specialized training or experience in rehabilitation.—A patient's condition must require the 24-hour availability of a physician with special training or experience in the field of rehabilitation. This need should be verifiable by entries in the patient's medical record that reflect frequent and direct and medically necessary physician involvement in the patient's care; i.e., at least every 2-3 days during the patient's stay. This degree of physician involvement, which is greater than would normally be rendered to a patient in a SNF, is an indicator of a patient's need for services generally available only in a hospital setting. A SNF patient's care would usually require only the general supervision of a physician, rather than the close supervision which hospital patients need.

2. Twenty-four hour rehabilitation nursing.—The patient requires the 24-hour availability of a registered nurse with specialized training or experience in rehabilitation. This degree of availability represents a higher level of care than would normally be found in a SNF. While a SNF patient may require nursing care, specialized rehabilitation nursing is generally not as readily available in such a facility.

3. A relatively intense level of physical therapy or occupational therapy and, if needed, speech therapy, social services, psychological services, or prosthetic-orthotic services.—The patient must require at least 3 hours a day of physical and/or occupational therapy, in addition to any other required therapies or services. In exceptional cases, an inpatient hospital stay for rehabilitation care can be covered even though the patient has a secondary diagnosis or medical complication that prevents him from participating in programs of physical or occupational therapy to the extent outlined above. Inpatient hospital care in these cases may be the only reasonable means by which even a low intensity rehabilitation program can be safely carried out. Documentation must be secured of the existence and extent of complicating conditions affecting the carrying out of a rehabilitation program to ensure that inpatient hospital care for less than intensive rehabilitation care is actually needed.

4. A multidisciplinary team approach to the delivery of the program.—A multidisciplinary team usually includes a physician, rehabilitation nurse, social worker and/or psychologist, and those therapists involved in the patient's care. At a minimum, a team must include a physician, rehabilitation nurse and one therapist.

5. A coordinated program of care.—The patient's records must reflect evidence of a coordinated program, i.e., documentation that periodic team conferences were held with a regularity of at least every 2 weeks to: (1) assess the individual's progress or the problems impeding progress; (2) consider possible resolutions to such problems; and (3) reassess the validity of the rehabilitation goals initially established. A team conference may be formal or informal; however, a review by the various team members of each other's notes would not constitute a team conference. The decisions made during such conferences, such as those concerning discharge planning and the need for any adjustment in goals or in the prescribed treatment program, must be recorded in the clinical record.

6. Significant practical improvement.—Hospitalization after the initial assessment is covered only in those cases where the initial assessment results in a conclusion by the rehabilitation team that a significant practical improvement can be expected in a reasonable period of time. It is not necessary that there be an expectation of complete independence in the activities of daily living, but there must be a reasonable expectation of improvement that will be of practical value to the patient, measured against his condition at the start of the rehabilitation program. For example, a multiple sclerosis patient's condition may have deteriorated as a result of a secondary illness. To be restored to a level of function before the secondary illness, the patient may require an intensive inpatient hospital rehabilitation program. While such a program would not restore the

level of function before multiple sclerosis developed, a return to pre-secondary illness level would be considered to be a "significant practical improvement" in the condition.

7. Realistic goals.—While there may be instances where an intense rehabilitation program may enable a Medicare patient to return to the labor market, vocational rehabilitation is generally not considered a realistic goal for most aged or severely disabled individuals. The most realistic rehabilitation goal for most Medicare beneficiaries is self-care or independence in the activities of daily living; i.e., self-sufficiency in bathing, ambulation, eating, dressing, homemaking, etc., or sufficient improvement to allow a patient to live at home with family assistance rather than in an institution. Thus, the aim of the treatment should be achieving the maximum level of function possible.

8. Length of the rehabilitation program.—Coverage should stop when further progress toward the established rehabilitation goal is unlikely or it can be achieved in a less intensive setting. In deciding whether further care can be carried out in a less intensive setting, both the degree of improvement which has occurred and the type of program required to achieve further improvement must be considered. In some cases an individual may be expected to continue to improve under an outpatient program. There are other situations where further improvement in the individual's ability to function relatively independently in the activities of daily living can be expected only if a multidisciplinary team effort is continued.

While occasional home visits and other trips into the community are factors in determining whether continued stay in the hospital is necessary, such excursions would not alone be a basis for concluding that further hospital care is not required. Planned home visits and trips to the community are frequently used to test the individual's ability to function outside the institutional setting and to assist in discharge planning for the individual.

It is also important to consider how close the patient may be to the planned end of his rehabilitation hospital stay when further progress becomes unlikely. If a patient is within a few days of discharge, it would usually not be appropriate to transfer him to a less intensive setting in another facility even though further progress in the hospital setting is unlikely. However, it could be appropriate to utilize a "swing bed" arrangement, if it exists in the same facility, for rendering necessary services to the patient pending discharge.

When discharge or transfer to another facility is appropriate, the cut-off point for coverage should not be the last day on which improvement actually occurred. Rather coverage should continue through the time it would have been reasonable for the physician, in consultation with the rehabilitation team, to have concluded that further improvement would not occur and to have initiated the patient's discharge.

Since discharge planning is an integral part of any rehabilitation program and should begin upon the patient's admittance to the

facility, an extended period of time for discharge action would not be reasonable after established goals have been reached, or after a determination has been made that further progress is unlikely or that care in a less intensive setting would be appropriate.

Effective Date: July 31, 1985.

MEDICARE PROGRAM

Hospital Insurance and Supplementary Medical Insurance Benefits (Parts A and B)

Use of Statistical Sampling to Project Overpayments to Providers and Suppliers

HCFAR 86-1

Purpose: HCFA and its Medicare contractors may use statistical sampling to project overpayments to providers and suppliers when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible.

Citations: 1815(a), 1842(a), and 1861(v)(1)(A)(ii) (42 U.S.C. 1395g(a), 1395u(a), and 1395x(v)(1)(A)(ii)); 42 CFR 401.108.

Pertinent History: The provider billed and was paid by Medicare for services to beneficiaries from September 1982 through July 1985. As result of a subsequent audit of the provider's Medicare claims, the intermediary discovered a large number of bills for medically unnecessary services. The intermediary also determined that the provider knew or should have known that the services were not covered and, therefore, was not entitled to have payment made to it for the services.

The intermediary considered conducting a case-by-case review in order to determine the amount the provider had been overpaid for the services. This

would have entailed an examination of all of the provider's beneficiary records for the period in question in order to identify those beneficiaries who had received unnecessary services. It also would have been necessary to tabulate the total amount that Medicare had paid the provider for each beneficiary. The intermediary decided that this method of determining the amount of the overpayment was not administratively feasible, given the volume of records involved and the cost of retrieving and reviewing all the beneficiary records for the period in question. The cost of identifying and calculating each individual overpayment itself would constitute a substantial portion of the amount the intermediary might reasonably be expected to recover. Further, the allocation of sufficient staff to reexamine all individual claims for the period in question would interfere with current claims processing activities to an unacceptable degree.

The intermediary notified the provider that, because of the volume of records and the costs of retrieving and reviewing all records for the period as discussed above, it intended to project the overpayment by reviewing a statistically valid sample of beneficiary records and that if it were determined that the provider had been overpaid for the sample cases, it would project the results (again using statistically valid methods) to the entire population of cases from which the sample had been drawn. This would result in a statistically accurate estimate of the total amount the provider had been overpaid for services to these beneficiaries.

The provider objected to the intermediary's use of sampling to project the overpayment on the following grounds:

1. There is no legal authority in the Medicare statute or regulations for HCFA or its intermediaries to determine overpayments by projecting the findings of a sample of specific claims onto a universe of unspecified beneficiaries and claims.
2. Section 1879 of the Social Security Act, 42 U.S.C. 1395pp, contemplates that medical necessity and custodial care coverage determinations will be made only by means of a case-by-case review.
3. When sampling is used, providers are not able to bill individual beneficiaries not in the sample group for the services determined to be noncovered.
4. Use of a sampling procedure violates the rights of providers to appeal adverse determinations.
5. The use of sampling and extrapolation to determine overpayments deprives the provider of due process.

(The succeeding presentation of our decision and supporting facts is applicable also to the use of sampling to project overpayments to suppliers (including physicians) whose claims are processed by Medicare carriers when 100 percent readjudication would be excessively costly or impractical.)

The Supreme Court has long recognized that the Federal Government possesses an inherent right to recover monies illegally or erroneously paid out. United States v. Carr, 132 U.S. 644, 650 (1890); Wisconsin Cent. R.R. v.

United States, 164 U.S. 190, 212 (1896). This right exists independent of statute. See United States v. Wurts, 303 U.S. 414, 416 (1938); Grand Trunk W. Ry. v. United States, 252 U.S. 112, 121 (1920). The Government may enforce its right of recoupment by reasonable means, and it may exercise that right without resorting to litigation by offsetting the amount against sums otherwise due. United States v. Munsey Trust Co., 332 U.S. 234, 239-240 (1947). Offsets against current or subsequent obligations may be used to prevent a recipient of Federal funds from retaining monies that are later found to have been unauthorized by the terms and conditions under which they were received. Wisconsin Cent. R.R. v. United States, supra, 164 U.S. at 211-212.

The Government's common law right of recoupment, and its corollary power of recovery by offset, are based on strong considerations of public policy. All funds at the disposal of the Government belong to the public. As custodian of these funds, a Federal agency has the fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. Accordingly, if the public's money has been expended in a manner not authorized by statute, the agency's obligation requires it to take administrative actions necessary to prevent an unjust enrichment by the recipient at the expense of the Federal treasury. See United States v. Wurts, supra, 303 U.S. at 415-416; Grand Trunk W. Ry. v. United States, supra, 252 U.S. at 120-121.

The common law right to recover Federal funds has been specifically recognized as being fully applicable to the Medicare program. Mt. Sinai Hospital v. Weinberger, 517 F.2d 329 (5th Cir. 1975); Wilson Clinic and Hospital, Inc.

v. Blue Cross, 494 F. 2d 50 (4th Cir. 1974). Moreover, the courts have also recognized that extrapolation based on a sample is a valid audit technique in cases arising under the Social Security Act. Illinois Physicians Union v. Miller, 675 F. 2d 151 (7th Cir. 1982); State of Georgia v. Califano, 446 F. Supp. 404 (N.D. Ga. 1977); New Jersey Welfare Rights Organization v. Cahill, 349 F. Supp. 501 (D.N.J. 1972); Rosado v. Wyman, 322 F. Supp. 1173 (E.D. N.Y. 1970), aff'd 402 U.S. 991 (1971). In view of the enormous logistical problems in determining massive overpayments in social welfare programs, sampling is the only feasible method available. State of Georgia v. Califano, supra; Illinois Physicians Union v. Miller, supra.

Congress has affirmed the Government's right to recover Medicare Trust Funds by reasonable means from those who have no right to retain them. Section 1815(a) of the Social Security Act, 42 U.S.C. 1395g(a), authorizes "necessary adjustments on account of previously made overpayments or underpayments" under Medicare Part A. Similarly, as to Part B of Medicare, section 1842(a), 42 U.S.C. 1395u(a), provides that carriers make determinations as to the amount of payments to be made to providers of services and other persons, and authorizes such audits of the records as may be necessary to assure that proper payments are made. In addition, section 1861(v)(1)(A)(ii) of the Act, 42 U.S.C. 1395x(v)(1)(A)(ii), provides for the "making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive." These statutory requirements, in effect, would be abrogated if sampling were not available to determine Medicare overpayments.

The imposition of such a result would be inconsistent with the settled principle that, when Congress creates a statutory right, the existence of appropriate remedies to enforce that right will be presumed in the absence of a clear indication of a contrary congressional intent. Texas & N.O.R.R. v. Brotherhood of Railway & Steamship Clerks, 281 U.S. 548, 569-570 (1939); Sullivan v. Little Hunting Park, Inc., 396 U.S. 229, 239 (1969).

Since HCFA's contractors process vast numbers of Medicare claims (for example, in fiscal year 1985, intermediaries received over 59.5 million Medicare claims and carriers received over 270.8 million claims), an interpretation that title XVIII of the Act mandates that a 100 percent review of cases be conducted before HCFA or its contractors can determine that providers or suppliers have been overpaid would make it virtually impossible for HCFA to implement these statutory provisions in many cases. A case-by-case review could require a significant diversion of staff from the ongoing claims process, and the cost of determining the amount of an overpayment would be prohibitively high unless a sampling method were used. To fulfill the congressional intent, HCFA must adopt realistic and practical auditing procedures. The alternative is to conclude that the intent of Congress was that, if case-by-case overpayment determinations are not administratively feasible, the Medicare Trust Funds must forego restitution of funds improperly obtained by providers and suppliers. We do not believe that was Congress' intent.

We also do not believe that the statutory provisions limiting provider or beneficiary liability preclude the use of sampling. In instances where Medicare coverage is denied because items or services furnished are not "medically

necessary" or constitute "custodial" care, section 1879 of the Act, 42 U.S.C. 1395pp (42 CFR 405.330), authorizes a limitation of the beneficiary's liability when the beneficiary did not know, and could not reasonably be expected to have known, that the items or services were not "medically necessary" or that they constituted "custodial" care. The Medicare program will make payments to the provider when both the beneficiary and the provider were without the requisite knowledge. When the beneficiary did not have such knowledge, but the provider did, liability for the denied services rests with the provider and the beneficiary's liability is waived. The beneficiary will be indemnified by the Medicare program if he or she has already paid the provider. See 42 U.S.C. 1395pp. Liability will rest with the beneficiary only when he or she knew or could have been expected to know that the items or services furnished were not "medically necessary" or were "custodial" in nature.

The use of sampling to determine overpayments for medically unnecessary services or custodial care does not deprive a provider of its right to bill those beneficiaries who knew or should have known that they were receiving these services. Under the governing regulation, 42 CFR 405.334, a beneficiary is presumed not to have had such knowledge unless he or she was notified in writing by the provider, the intermediary, or the Peer Review Organization (PRO). For example, when a beneficiary who is receiving a course of treatment has received a previous denial notice stating that similar items or services were not covered, the previous denial notice would constitute evidence that the beneficiary did or should have had knowledge of noncoverage. See 42 CFR 405.334 for examples of

acceptable written notice to a beneficiary. The operation of this provision effectively serves to resolve most limitation of liability questions in the beneficiary's favor. However, a provider that wishes to bill individual beneficiaries not included in the sample can identify those individuals who were previously informed that they were receiving noncovered services by inquiring of the intermediary or PRO as to whether it sent a notice to the individual. (The provider presumably did not give notice to the beneficiary that the services were not covered because, if it had, it is unlikely that it would have billed Medicare for the services.)

Even if we assume that a provider is effectively precluded from billing a beneficiary in certain cases, this assumption would not bar the Government from its fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. As between the provider and the Government, strong considerations of public policy favor recovery. On the other hand, the provider had the responsibility to know and should have known that the services furnished were not medically necessary. Moreover, as the United States Court of Appeals for the Fifth Circuit recognized in Mt. Sinai Hospital of Greater Miami v. Weinberger, 517 F. 2d 329 (5th Cir. 1976), the provider assumes substantial responsibility for overpayments.

> . . . the hospital is not a neutral, innocent party in this three-way transaction between HEW, Medicare beneficiary and Medicare provider. The decision to provide a service is made by the individual attending physician, who is far better informed on both the medical issue and the

scope of Medicare coverage than is the patient-beneficiary. The physician is either an employee of the hospital or a doctor with staff privileges. Whatever else the granting of staff privileges may connote, it is clear to us that it involves a delegation by the hospital of authority to make decisions on utilization of its facilities. 534 F. 2d at 338.

In reimbursing providers, HCFA has to balance the need to process billings rapidly in order that a provider's liquidity needs do not suffer and the need to verify that the claims submitted are for services covered by the Act. Mixed into this balance is the volume of claims which must be reviewed. Considering the volume of claims (as cited earlier to be over 330.3 million for fiscal year 1985), it is virtually impossible to examine each bill submitted by a provider or supplier in sufficient detail to assure before payment in every case that only medically necessary services have been provided. Therefore, as a practical matter, HCFA and its contractors must depend on the provider to submit claims for services that are covered by the Act. In most cases, this reliance is justified. However, if HCFA or its contractors later have reason to make an indepth and careful review of claims for services which had been previously paid and discover that medically unnecessary services have been provided, a provider cannot cry "foul" when these payments (to which they were never legally entitled) are recovered.

Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis

for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

The provisions of the statutes and regulations provide a constitutionally sufficient means by which the provider may challenge an overpayment determination. In cases of denials made through sampling which are based on medical necessity or custodial care, section 1879 of the Act, 42 U.S.C. 1395pp, permits the provider to assert the same appeal rights that an individual has under the statute when the individual does not exercise his rights to appeal. Under Part A, these rights include an opportunity for reconsideration (42 CFR 405.710-405.716), an oral evidentiary hearing by an administrative law judge (42 CFR 405.720-405.722), Appeals Council review (42 CFR 405.701(c) and 405.724), and finally judicial review if the amount in controversy is $1,000 or more (42 CFR 405.730; 42 U.S.C. 1395ff(b)(2)). In cases that do not involve medical necessity or custodial care, 42 CFR 405.370, et seq. sets out the applicable procedures through which current payments may be suspended (offset) to recover an overpayment under the Medicare program. Under 42 CFR 405.371, a provider is

given notice as to the basis for the overpayment and an opportunity to respond before an intermediary may suspend current Medicare reimbursement. 42 CFR 405.372, in conjunction with 42 CFR 405.370(b), forestalls any suspension pending consideration of any statement by the provider in opposition to the notice of suspension. Finally, if it is determined that a suspension should go into effect, written notice of the determination will be sent to the provider or other supplier. The notice will contain specific findings on the conditions upon which the suspension was based and an explanatory statement for the final decision. Thus, the administrative scheme provides sufficient means for a provider to challenge overpayment determinations that are made on the basis of sampling.

Under Part B, suppliers who accept assignment may request a Medicare carrier to review a payment determination with which the supplier disagrees (42 CFR 405.807). If the supplier is dissatisfied with the carrier's review determination, the supplier may request a hearing before a carrier hearing officer if the amount in controversy is $100 or more (42 CFR 405.820). There are no further appeals available under Part B. In U.S. v. Erika, Inc., 456 U.S. 201 (1982), the Supreme Court ruled unanimously that, under current law, the Part B hearing is rightfully the final step in the Part B appeals process.

In summary, the use of sampling is a reasonable and cost effective method of projecting overpayments under Medicare. It is not unfair to a provider or supplier to hold it accountable for the receipt of Medicare funds to which it is not entitled under the statute. To the contrary, allowing a provider or supplier improperly to retain large sums of program funds would be unfair to the intended

beneficiaries of Medicare and to the taxpayers who contribute to the trust funds. As the Supreme Court held in Richardson v. Perales, 402 U.S. 389 (1971), the system must not only be fair, but it must work.

Ruling: Accordingly, it is held that the use of statistical sampling to project an overpayment is consistent with the Government's common law right to recover overpayments, the Medicare statute, and the Department's regulations, and does not deny a provider or supplier due process. Neither the statute nor regulations require that a case-by-case review be conducted in order to determine that a provider or supplier has been overpaid and to determine the amount of overpayment.

Effective date: This Ruling is effective February 20, 1986.

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